

Attorney Docket No.: UT-0031
Inventors: Mayer-Proschel et al.
Serial No.: 09/813,429
Filing Date: March 21, 2001
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REMARKS

Claims 1-4 are pending in the instant application. Claims 2-4 have been withdrawn from consideration by the Examiner and subsequently canceled without prejudice by Applicants in this response. Claim 1 has been rejected. Claim 1 has been amended. Support for amendments to claim 1 is provided in the specification at page 5, lines 2-3, page 6, lines 24-28, and Example 1. No new matter has been added by these amendments. Reconsideration is respectfully requested in light of these amendments and the following remarks.

I. Finality of Restriction Requirement

The Examiner has made final the restriction requirement mailed on August 13, 2003. Thus, in an earnest attempt to advance the prosecution, Applicants have canceled non-elected claims 2-4. In light of the finality of this restriction requirement, Applicants reserve the right to file a divisional application to the canceled subject matter.

II. Rejection of Claim 1 under 35 U.S.C. 112, first paragraph

Claim 1 has been rejected under 35 U.S.C. 112, first paragraph, for lack of enablement. The Examiner has acknowledged the specification to be enabling for a method of isolating human

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neuroepithelial precursor cells from neural tissue from human embryos after first culturing on fibronectin/laminin, and then after, using structurally known and definable antibodies to A2B5, NG2, and eNCAM. However, the Examiner suggests that the specification does not reasonably provide enablement for a method of using generic "human fetal cells" committed to a different tissue fate, or a method of using antibodies to structurally and functionally uncharacterized epitopes/markers (NG2).

Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have amended claim 1 to specify that the human fetal tissue used is at a stage at which neurogenesis occurs. As acknowledged by the Examiner, support for this amendment can be found in the specification on page 5, lines 2-3.

Further, it is respectfully pointed out that both monoclonal and polyclonal NG2 antibodies are commercially available from Chemicon International. Catalog descriptions for both the monoclonal (see catalog # AB5320) and polyclonal NG2 (catalog # MAB5384) from the Chemicon International online catalog (www.chemicon.com) are included herewith. Thus, contrary to the Examiner's suggestion, no experimentation is required to identify the structure and function of NG2 antibodies that work with the

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present invention as these antibodies are commercially available.

MPEP 2164.05(a) states that the specification need not disclose what is well known to those skilled in the art, and preferably omits that which is well known to those skilled in the art and already available to the public. As evidenced by the online Chemicon pages submitted herewith, NG2 antibodies are known and available to the public. Thus, in accordance with MPEP 2164.05(a), further details in the specification regarding structure or function of NG2 are not needed.

Withdrawal of this rejection under 35 U.S.C. 112, first paragraph, is respectfully requested in light of the above amendments to the claims and the above remarks.

III. Rejection of claims under 35 U.S.C. 112, second paragraph

Claim 1 has been rejected under 35 U.S.C. 112, second paragraph, as being indefinite and incomplete for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. In particular, the Examiner suggests that culturing is normally carried out in medium and that the claim is incomplete without this term with respect to culturing conditions.

Thus, in an earnest effort to advance the prosecution, claim

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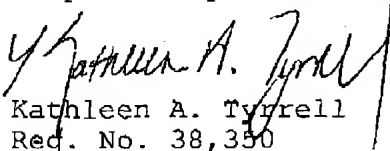
1 has been amended to recite that culturing of the human fetal cells occurs in medium containing fibroblast growth factor and chick embryo extract. Support for this amendment can be found at page 5, lines 31-33, page 6, lines 24-28, and Example 1 of the specification.

Withdrawal of this rejection under 35 U.S.C. 112, second paragraph, is respectfully requested in light of these amendments to the claims.

IV. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,


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**MOUSE ANTI-NG2 CHONDROITIN SULFATE PROTEOGLYCAN
MONOCLONAL ANTIBODY**

CATALOG NUMBER: MAB5384

LOT NUMBER:

QUANTITY: 100 µg

CONCENTRATION: 1.0 mg/mL

SPECIFICITY: NG2 Chondroitin Sulfate Proteoglycan. MAB5384 reacts with native, recombinant and protein from cells which express NG2.

BACKGROUND: NG2 is a high molecular weight, integral membrane chondroitin sulfate proteoglycan. It is found on the surfaces of an unusual class of glial cells within the developing and mature central nervous system that have the properties of oligodendrocyte precursor cells (i.e., O-2A progenitor cells). NG2 is also found on the surfaces of chondroblasts, proliferating capillary endothelial cells, some human melanoma cell lines, and on leukemic blasts in childhood acute lymphoblastic leukemia. The NG2 proteoglycan is likely to play a role in regulation of cell motility, axon outgrowth and the cellular responses to platelet-derived growth factor.

IMMUNOGEN: Cell line expressing a truncated form of NG2.

ISOTYPE: IgG₁

APPLICATIONS: Western blot. Recognizes the >280 kD NG2 protein. Suggested blocking buffer is 5% dry milk in TBST.
Immunocytochemistry: 1:200-1:500 on oligodendrocyte precursor cells.
Immunohistochemistry. It is suggested that the tissue used is only lightly fixed (4% paraformaldehyde for less than 2 hours, etc.). Avoid overfixing tissue. Suggested blocking buffer is 2-4% normal serum. Suggested antibody dilution buffer is PBS containing 0.1% Triton X100.
ELISA (direct)
Optimal working dilutions must be determined by end user.

SPECIES REACTIVITIES: Rat. The antibody may also work on human but this has not yet been determined.

FORMAT: Purified immunoglobulin.

PRESENTATION: Liquid in 0.02M Phosphate buffer, containing 0.25M NaCl and 0.1% azide.

STORAGE/HANDLING: Maintain at 2-8°C in undiluted aliquots for up to 6 months.

For research use only; not for use as a diagnostic.

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3-10-2003/MAB5384/CB



**RABBIT ANTI-NG2 CHONDROITIN SULFATE PROTEOGLYCAN
POLYCLONAL ANTIBODY**

CATALOG NUMBER: AB5320

LOT NUMBER:

QUANTITY: 100 µg

CONCENTRATION: 1.5 mg/mL

SPECIFICITY: NG2 Chondroitin Sulfate Proteoglycan. AB5320 identifies both the intact proteoglycan and the core protein by Western blot and ELISA.

BACKGROUND: NG2 is a high molecular weight, integral membrane chondroitin sulfate proteoglycan. It is found on the surfaces of an unusual class of glial cells within the developing and mature central nervous system that have the properties of oligodendrocyte precursor cells (i.e., O-2A progenitor cells). NG2 is also found on the surfaces of chondroblasts, proliferating capillary endothelial cells, some human melanoma cell lines, and on leukemic blasts in childhood acute lymphoblastic leukemia. The NG2 proteoglycan is likely to play a role in regulation of cell motility, axon outgrowth and the cellular responses to platelet-derived growth factor.

IMMUNOGEN: Immunoaffinity purified NG2 Chondroitin Sulfate Proteoglycan from rat.

APPLICATIONS: Western blot: 1:600-1:1,500
Immunocytochemistry: 1:150-1:600.
Immunohistochemistry: 1:200 on embryonic mouse brain tissue using an Alexa Fluor conjugated secondary antibody. It is suggested that the tissue used is only lightly fixed (4% paraformaldehyde, etc.). Avoid overfixing tissue.
Immunoprecipitation: 2 µg/mL
ELISA: 1:1,500-1:3,000
Optimal working dilutions must be determined by end user.

SPECIES REACTIVITIES: Human, mouse, rat and monkey.

FORMAT: Purified immunoglobulin.

PRESENTATION: Liquid in PBS containing 0.02% azide.

STORAGE/HANDLING: Maintain frozen at -20°C in undiluted aliquots for up to 6 months. Avoid repeated freeze/thaw cycles.

REFERENCE: *Perspect. Develop. Neurobiology* (1996) 3:245-259.
Reubinoff, B.E., et al., *Nature Biotechnology* (2001) 19:1134-1140.
Carletti, B., et al., *J. Neuroscience* (2002) 22:7132-7146.
Belachew, S., et al., *J. Neuroscience* (2002) 22:8553-8562.
Maxeiner, S., et al., *Neuroscience* (2003) 119:689-700.

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